

No.12-37

June 27, 2012
Eisai Co., Ltd.

EISAI RECEIVES RUSSIAN REGULATORY APPROVAL FOR FIRST PRODUCT— ANTIEPILEPTIC AGENT ZONEGRAN®

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) announced today that the Ministry of Health and Social Development of the Russian Federation has approved the antiepileptic agent Zonegran® (zonisamide) as an adjunctive therapy in the treatment of adult epilepsy patients with partial seizures. Zonegran is the first product for which Eisai has received approval for in Russia.

The Russian pharmaceuticals market constitutes the 11th largest in the world and is expected to see high growth going forward¹⁾. In light of this, Eisai established a representative office, overseen by its U.K. subsidiary Eisai Europe Limited, in Moscow in October 2007, and has since been working to complete product registration procedures. The company has already submitted marketing authorization applications for three more products—anticancer agent Halaven® (eribulin mesylate) and AMPA-type glutamate receptor antagonist FYCOMPA® (perampanel), both of which are global products, and antiepileptic agent Exalief® (brand name in the EU: Zebinix®, under license from the originator BIAL-Portela & Ca S.A.).

Zonisamide is an antiepileptic drug (AED) originally created by Dainippon Pharmaceutical Co., Ltd. (currently Dainippon Sumitomo Pharma Co., Ltd.), for which Eisai holds development, manufacturing and marketing rights in Russia as well as in Europe, the United States and Asia.

Eisai has set the goals of entering the world’s top 20 largest pharmaceuticals markets by fiscal 2015 and making contributions to more than 500 million patients as part of the company’s great globalization era strategy outlined in its mid-term strategic plan “HAYABUSA.” Eisai’s enhancement of its product lineup and marketing framework in Russia underscores the company’s commitment to increasing the benefits provided to patients and their families across the region.

1) David Campbell and Mandy Chui. Russian Healthcare and the Pharmaceutical Industry.
http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Pharma_Shake-up_Imperatives_3_10.pdf

**[Please refer to the following notes for an outline of Zonegran and further information on
Eisai’s Great Globalization Strategy Set Out in the Mid-term Strategic Plan “HAYABUSA” and the
Russian pharmaceuticals market.]**

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[Notes to editors]

1. **About Zonegran® (zonisamide)**

Zonisamide, originally created by Dainippon Pharmaceutical Co., Ltd. (currently Dainippon Sumitomo Pharma Co., Ltd.), is an antiepileptic drug (AED) with multiple mechanisms of action, including inhibition of Na/Ca channels. Eisai is currently developing and marketing zonisamide in Europe, the United States and the Asia region. Zonisamide was approved in Europe in March 2005 as an adjunctive therapy in the treatment of adult epilepsy patients with partial seizures, with or without secondary generalization. In May 2012, Eisai received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) for extending the use of the drug as monotherapy for the treatment of partial seizures in adults with newly diagnosed epilepsy. Dainippon Pharmaceutical received approval in 1989 to market zonisamide in Japan, where it is sold under the brand name Excegran®.

2. **Eisai's Great Globalization Strategy Set Out in the Mid-term Strategic Plan "HAYABUSA"**

Eisai has set the goals of entering the world's top 20 largest pharmaceuticals markets by fiscal 2015 and making contributions to more than 500 million patients as part of the company's great globalization era strategy outlined in its mid-term strategic plan "HAYABUSA." Of the eight countries (Canada, Brazil, Russia, Australia, Turkey, Poland, Mexico, and Venezuela) that Eisai announced it would enter when the "HAYABUSA" Plan was launched in March 2011, the company has already established sales subsidiaries in countries other than Russia, namely Australia (January 2006), Canada (April 2010), Brazil (April 2011) and Mexico (August 2011).

3. **About the Russian Pharmaceuticals Market**

The Russian pharmaceuticals market constitutes the 11th largest in the world and is projected to grow an average of approximately 10% going forward. The Russian health insurance system is comprised of state-funded obligatory medical insurance and voluntary privately-purchased medical insurance. In principle, the obligatory medical insurance system offers no-cost access to basic healthcare services and all inpatient medicines provided by public medical institutions. Although patients must cover the entire cost of outpatient medicines themselves, drugs included in the Essential Drugs List (EDL) as well as drugs for certain specified illnesses are provided free of charge through federal and regional prescription drug access programs.